

## **Substituted p-Phenylenediamines Category – Comments of Environmental Defense**

(Submitted via Internet May 15, 2002)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the Substituted p-Phenylenediamines Category.

In its Test Plan for the substituted p-phenylenediamine category, the Rubber and Plastic Additives (RAPA) Panel of the American Chemical Council proposes that a number of antioxidants based on p-phenylenediamine and having similar structural, physicochemical, and toxicological characteristics be considered as a category. The Test Plan and Robust Summaries submitted for these chemicals are well organized, and the data are clearly presented and sufficiently complete to support interpolation and/or extrapolation to assess data gaps where they exist. Background material presented in the Test Plan also indicates that these chemicals are used only in finished products, and thus there would appear to be limited chance of environmental or consumer exposure. The Test Plan is supported by numerous, well-designed and clearly described studies. Most of these studies were conducted under GLP. Further, all available data for the parent p-phenylenediamine and substituted p-phenylenediamines described here as well as in other literature reviewed indicate these compounds are negative carcinogens when tested in animals. Therefore, we support consideration of the p-phenylenediamines as a category and agree that no additional testing is necessary. Our specific comments are limited to the following:

1. An earlier Test Plan/Robust Summary submitted by RAPA for the Substituted Diphenylamines included considerable data for the base chemical diphenylamine. Similar data for the base chemical of the substituted p-phenylenediamines, p-phenylenediamine, are not included in the present Test Plan/Robust Summary. Since p-phenylenediamine is a likely degradation and/or metabolic product of the substituted phenylenediamines we believe this is an omission of critical data. That is, the carbon-nitrogen bond of the p-phenylenediamines is much weaker than the carbon-carbon bond of the diphenylamines making p-phenylenediamine a likely degradation and/or metabolic product of compounds in this category. p-Phenylenediamine has been the subject of considerable research, and including discussion of it would further enhance a thorough submission.
2. Data in the Robust Summaries indicate that these chemicals hydrolyze rapidly. The data do not, however, describe the hydrolysis products. As discussed above, a likely hydrolysis product would be p-phenylenediamine, thus providing a second reason to list data for this chemical.
3. The substituted p-phenylenediamines hydrolyze rapidly in pure water, but degrade very slowly in aqueous sludge. Thus, they may be tightly adsorbed onto the organic matter in sludge and could thus persist in the environment to possibly result in bioaccumulation and toxicity to aquatic organisms if they should somehow be released. This possibility should be addressed.
4. Some members of the category are irritating or corrosive to skin but are otherwise of relatively low toxicity to mammals. That fact was not made obvious in the Test Plan and should be addressed. RAPA may also want to point out that some of the toxicity observed in mammals may have resulted from gastrointestinal irritation that occurred as a result of gavage dosing, a situation that is unlikely to occur with humans.
5. No synonyms are listed for these chemicals. Each has at least one commercial synonym "Santoflex #, etc." It would be helpful to include a list of these synonyms.

Thank you for this opportunity to comment.

Hazel B. Matthews, Ph.D.  
Consulting Toxicologist, Environmental Defense

Karen Florini  
Senior Attorney, Environmental Defense